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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,760

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John A. Dyjach

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EXAMINER

HOLMES, REX R

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/730,760	<b>Applicant(s)</b> DYJACH ET AL.	
	<b>Examiner</b> REX HOLMES	<b>Art Unit</b> 3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 29-35 and 61 are rejected under 35 U.S.C. 102(a/e) as being anticipated by Stahmann et al. (U.S. Pub. 2003/0097155 hereinafter “Stahmann”).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

3. Regarding claims 29-31 and 61, Stahmann discloses a device with a plurality of channels including two ventricular and one atrial (20, 30, 40), with a plurality of electrodes (23, 33, 43), a controller (10), a memory (12), and a communication circuit (80). Stahmann further discloses that the device stimulates and senses the heart and can be used to provide resynchronization therapy (¶¶ 9, 15, 23-26). Stahmann further

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discloses that the device senses and records data to memory during intrinsic and paced beats (¶ 15). Stahmann further discloses that the data can be displayed as a trend and further that the communication circuit transmits the data to an external device (¶¶ 13, 15, 34). Stahmann further discloses that the sense signals from each channel are recorded. Stahmann further discloses that the electrogram that is recorded from each channel provides a record of depolarizations and repolarizations that occur during either intrinsic or paced beats. It is noted that the recorded electrograms include data as to the success level for the delivery of the CRT therapy with respect to time and cardiac events (¶¶ 13-15).

4. Regarding claims 32-33, Stahmann discloses that the device includes a memory that contains the prescribed CRT data, and record CRT data (¶¶ 13, 15, 35, 39).

5. Regarding claims 34-35, Stahmann discloses that the device records pacing information into memory, including atrial tracking (¶¶ 19-22).

6. Note: the limitations of "the controller ... being adapted to ... recording of data, the recorded data including..." is a function use recitation. Any RAM that records ECG data is capable of meeting the function use recitation of "recording data including data to measure. The claims has not set forth that this data is measured, but only memory to record it. Likewise the last paragraph of claim 29 only requires a communication circuit that transmits data. The limitation of "for presentation of data trends" happens outside the claimed structure and is not being positively recited.

***Claim Rejections - 35 USC § 102/103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 36-48 are rejected under 35 U.S.C. 102(a) as anticipated by Stahmann et al. (U.S. Pub. 2003/0097155 hereinafter "Stahmann") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stahmann.

9. Regarding claims 36-48, It is noted that the recitation that the controller is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. In the instant case, Stahmann discloses a device with a programmable microprocessor that trends, multiple sensing channels, and a memory for storing the sensed data (¶¶13, 15, 34). Therefore, Stahmann discloses a device with a controller that is capable of performing the limitations.

10. In the alternative, Stahmann discloses the essential features of the claimed invention as described above except not explicitly data trends, time associated with recorded data, and trend samples of data. However, it is well known in the art to include data trends, time associated with recorded data, and trend samples of data to yield the predictable results of optimizing pacing delay between two or more sites within the heart by trending a stream of data to characterize a patient's status and to show worsening and/or improving condition with respect to the paced heart.

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11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stahmann et al. to include data trends, time associated with recorded data, and trend samples of data to yield the predictable results of optimizing pacing delay between two or more sites within the heart by trending a stream of data to characterize a patient's status and to show worsening and/or improving condition with respect to the paced heart.

12. Claims 49-60 are rejected under 35 U.S.C. 102(a) as anticipated by Stahmann et al. (U.S. Pub. 2003/0097155 hereinafter "Stahmann") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stahmann in view of Kramer et al. (U.S. Pub. 2002/0133198).

13. Regarding claims 49-50, 52-55 Stahmann discloses a device with a plurality of channels including two ventricular and one atrial (20, 30, 40), with a plurality of electrodes (23, 33, 43), a controller (10), a memory (12), and a communication circuit (80). Stahmann further discloses that the device stimulates and senses the heart and can be used to provide resynchronization therapy (¶¶ 9, 15, 23-26). Stahmann further discloses that the device senses and records data to memory during intrinsic and paced beats (¶ 15). Stahmann further discloses that the data can be displayed as a trend and further that the communication circuit transmits the data to an external device (¶¶ 13, 15, 34). Stahmann further discloses that the claimed invention transmits data to an external programmer that has a display to visually display the trended data (¶¶ 13, 15, 33, 38; Fig. 2). Stahmann further discloses that the sense signals from each channel are recorded. Stahmann further discloses that the electrogram that is recorded from each

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channel provides a record of depolarizations and repolarizations that occur during either intrinsic or paced beats. It is noted that the recorded electrograms include data as to the success level for the delivery of the CRT therapy with respect to time and cardiac events (¶¶13-15). It is inherent that programmer includes a memory, controller, and telemetry circuits since the programmer wirelessly receives data from the implantable device and displays it on a screen.

14. Regarding claims 51, 58-59, Stahmann discloses that the device includes a memory that contains the prescribed CRT data, and record CRT data (¶¶ 13, 15, 35, 39).

15. Regarding claims 56-57, It is noted that the recitation that the controller is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. In the instant case, Stahmann discloses a device with a programmable microprocessor that trends, multiple sensing channels, and a memory for storing the sensed data (¶¶13, 15, 34). Therefore, Stahmann discloses a device with a controller that is capable of performing the limitations.

16. Regarding claim 60, Stahmann discloses that the device uses triggers to start recording data (¶33).

In the alternative regarding claims 49-60, Stahmann discloses that the device transmits data to an external programmer via a telemetry signal, but Stahmann does not specifically disclose the programmer includes a memory, controller or telemetry circuit. However, Kramer discloses a system that includes a implantable device and an external programmer that includes a memory (e.g., element 704); a controller (e.g., 706); a

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communication circuit (e.g., element 712); and a monitor (e.g., element 648). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stahmann, with the external programmer that has a memory, controller and communication circuitry as taught by Kramer, since such a modification would provide the predictable results of a programmer that has the circuitry required to operate for providing an external programmer that can communicate, display and analyze data from and implantable device.

### ***Response to Arguments***

17. Applicant's arguments regarding claims 29-35 and 49-60, that Stahmann fails to record data that includes data to measure the success level for delivery of the prescribed CRT sensed from a second site. Examiner respectfully disagrees.

Stahmann further discloses that the sense signals from each channel are recorded.

Stahmann further discloses that the electrogram that is recorded from each channel provides a record of depolarizations and repolarizations that occur during either intrinsic or paced beats (¶¶13-15). It is noted that the recorded electrograms include data as to the success level for the delivery of the CRT therapy with respect to time and cardiac events. Since the device records during intrinsic and paced beats, it includes the essential information regarding timing, delivery of pacing energy, and resulting intrinsic beats.

18. Next the applicant argues that there is no support in Stahmann for a controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time. The examiner respectfully disagrees. Stahmann



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discloses that it trends the sensed data. As indicated above, Stahmann further discloses that the electrogram that is recorded from each channel provides a record of depolarizations and repolarizations that occur during either intrinsic or paced beats (¶¶13-15). Trending an electrogram that records depolarizations and repolarizations that occur during either intrinsic or paced beats includes data regarding the success and timing of paced events for each chamber.

19. Regarding the adapted to language. It is noted that the recitation that the controller is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. In the instant case, Stahmann discloses a device with a programmable microprocessor that trends, multiple sensing channels, and a memory for storing the sensed data (¶¶13, 15, 34). Thus Stahmann is capable of sensing, storing data into memory, and trending the sensed/stored data.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./  
Examiner, Art Unit 3762

/George R Evanisko/  
Primary Examiner, Art Unit 3762